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Applicant's Name: Lawrence H. Thompson

Serial No. (Control No.): 09/637,962 Examiner: Regina M. Deberry

Filing Date: August 11, 2000 Art Unit: 1647

Application Title: Therapeutic Methods for Treating Subjects With a Recombinant Erythropoietin Having High Activity and Reduced Side Effects

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Lawrence H. Thompson Art Unit 1647
Serial No. 09/637,962
Filed August 11, 2000
Confirmation No. 8001
For THERAPEUTIC METHODS FOR TREATING SUBJECTS WITH A RECOMBINANT ERYTHROPOIETIN HAVING HIGH ACTIVITY AND REDUCED SIDE EFFECTS
Examiner Regina M. Deberry

15/D
M.G.J
3/24/03

March 13, 2003

AMENDMENT B

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

This amendment supplements Amendment A as filed January 9, 2003 in response to the Office action mailed September 9, 2002. Please enter the following amendments:

IN THE SPECIFICATION:

Please replace the paragraph beginning at page 15, line 4 with the following rewritten paragraph:

As mentioned in above, erythropoietins prepared from different DNA (genomic or cDNA) and/or in different cell lines have different glycosylation patterns and other attributes resulting in glycoproteins with differing biological activities. In the case of Epoetin Omega, broad peak fractions selected from a final isoelectric purification step, *in vivo* assay results using a polycythemic mouse assay typically show a range from about 40,000 to about 65,000 IU/mg. More narrowly selected peak fractions have an *in vivo* activity in the range of 90,000 IU to 120,000 IU per mg. For Epoetin Alfa, *in vivo* activity of pharmaceutical preparations typically are in the range of about 110,000 IU per mg. Pharmaceutical preparations are tested in a quality assurance / quality control process using the polycythemic mouse assay before being released for human use.

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